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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,379	03/16/2000	Lecon Woo	1417Y P 418	2449

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EXAMINER

NOLAN, SANDRA M

ART UNIT

PAPER NUMBER

1772

9

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/526,379	WOO ET AL.
Examiner	Art Unit	
Sandra M. Nolan	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 05 March 2002.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-41 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-41 is/are rejected.

7)  Claim(s) 12 and 34 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6)  Other: \_\_\_\_\_

**DETAILED ACTION**

***Claims***

1. Claims 1-41 are pending.

***Election/Restriction***

2. Upon reconsideration, all claims previously withdrawn from consideration have been rejoined, the election/restriction requirement discussed in the Office Action of August 22, 2002 (Paper No. 5) is hereby withdrawn.

***Information Disclosure Statement***

3. The information disclosure statement submitted on February 8, 2002 (Paper No. 6) was considered by the examiner.

***Request for Clean Copy of Claims***

4. In view of the large number of claims and the amendments thereto, it is requested that applicants supply a clean copy of all of the pending claims in the next office action.

***Rejections Withdrawn***

5. All of the 35 USC 112 and 35 USC 103 rejections set out in sections 10 through 15 of Paper No. 5 are withdrawn in view of applicants' amendments and arguments in the response dated March 5, 2002 (Paper No. 8).

***Claim Objection***

WID- 6. Claims 12 and 34 are objected to under 37 CFR 1.75 as being substantial duplicates of claims 11 and 34, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a

slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***New Rejections***

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-12, 31-35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 31 and 35 recites the limitation "wherein the second component is a cyclic olefin" in lines 1+. There is insufficient antecedent basis for this limitation in claims 1 and 21, from which they depend. Note that claims 1 and 21 call for the "cyclic olefin containing polymers". [Emphasis added.]

Likewise, claim 37 depends on claim 35 and call for an ethylene/alpha-olefin copolymer, but no such copolymer is recited in claim 35.

Please clarify the claims.

**Claim Rejections - 35 USC § 103**

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-3, 13, 16-22, 24, 25, and 38-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Barney et al (US 6,203,535 B1) in view of Galante (US-5,272,210).

Barney is discussed in section 14 of Paper No. 5. It basically discloses/suggests most of the structural features of applicants' containers (col. 4, lines 8+) as well as the electron beam irradiation of same (col. 41, lines 57+). Barney's containers are polymeric (col. 4, lines 27-47). The abstract teaches that Barney's containers are used in applications where peelable seals between chambers of a container for diluents and medicaments are put under pressure to cause them to rupture in order to mix the ingredients in the separate chambers before/during use. Barney fails to teach blends of ethylene/acrylate ester (E/A)copolymers with ethylene/propylene (E/P) copolymers or the use of 1 to 6% ethylene in the E/A copolymers.

Galante teaches blends of 60-80% E/A copolymers ("EMAC" copolymers at col. 8, Table I) containing 1 to 7% ethylene (abstract) with 20 to 40% E/P copolymers (also in table I). The blends produce films having good flexibility at low temperatures

(abstract) and are useful in making bags for medical fluids, such as blood and plasma (col. 8, lines 32-33).

Barney and Galante are analogous because they both deal with polymeric containers.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the polymer blends of Galante when making the containers of Barney in order to produce containers having good flexibility at low temperatures.

The motivation to employ the blends of Galante in the containers of Barney is found in the abstract of Galante as well as at col. 8, lines 32-33 of Galante, where the low temperature flexibility of films made from the blends and the usefulness of such films in making bags for blood and plasma are discussed. It is deemed desirable to make films for bags to hold blood, plasma and the like in order to store separate components of such fluids for later mixing, e.g., components of whole blood, while assuring that the bags would be flexible when cooled so that they do not deteriorate during cold storage.

The selection of suitable levels of irradiation (per applicants' claim 21) would be a matter of engineering choice depending upon the properties desired in the final containers.

The properties recited in applicants' claim 22 would be expected in the films of Galante because of the similarity of the polymers used in the claimed blends to those of Galante.

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barney taken with Galante and further in view of Occhiello et al (EPO 0423499 A2).

Barney and Galante are discussed above. Neither teaches electron irradiation in the presence of oxygen.

Occhiello is discussed in section 15 of Paper No. 5. It shows that electron beam/oxygen treatment enhances the printability of films (page 2, lines 44+).

All of the cited references deal with polymeric materials and are therefore analogous.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the electron beam/oxygen treatment of Occhiello to treat the surface of the containers suggested by the above combination of Barney and Galante in order to render those surfaces more printable.

The motivation to apply the electron beam/oxygen treatment of Occhiello to the containers suggested by the combination of Barney and Galante is found at page 2, lines 44+ of Occhiello, where the use of such treatment to enhance printability is taught. It is deemed desirable to make containers printable in order to eliminate a labeling step during the manufacture of such containers and to make it easier for medical personnel to put customized labels or indicia on the surface of such containers.

12. Claims 1, 2, 4-8, 13-24, 26-30, and 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney in view of Wilhoit et al (US 5,928,740).

Barney is discussed above.

It fails to teach the blends of E/P copolymers having varying melting points ands being made using single site catalysts as recited in applicants' claims.

Wilhoit teaches the production of films (abstract) from blends containing two or three E/P copolymers (cols. 7 and 8). The first E/P copolymers has a melting point of 55 to 75 degrees C and is single-site catalyzed (col. 7, lines 24-29 and 37-38). The second E/P copolymer has a melting point of 85 to 110 degrees C (col. 7, lines 59-64). The third E/P copolymer melts at 115 to 130 degrees C (col. 8, lines 27-33). The first is used at amounts of 20 to 35 % (col. 7, lines 55-58). The second is used in amounts of from 25 to 60% (col. 8, lines 14-26). Wilhoit's blends are used in applications where they may be crosslinked with irradiation at dosages of 1 to 10 Mrad (col. 10, lines 22-24). Applicants have acknowledged on page 6 of their response (Paper No. 8) that 1-10 Mrad is equivalent to 10 to 100 kGy. In the abstract, films made from Wilhoit's blends are said to be heat sealing and puncture resistant.

Barney and Wilhoit are analogous because both deal with polymeric materials that may be irradiated.

The motivation to employ the Wilhoit blends in making films for the containers of Barney is found in the Wilhoit abstract, where the heat sealability and puncture resistance of the Wilhoit films are discussed. It is deemed desirable to make containers from films that are sealable and puncture resistance in order to facilitate the production of the seams in the Barney containers via heat sealing and in order to lessen the chance that the containers would be punctured and their contents spilled and/or contaminated.

The melt flow rates (per applicants' claims 5, 6, 27, and 28) would be expected to correspond to the melting points of the E/P polymers employed.

The properties recited in applicants' claim 22 would be expected in the films of Wilhoit because of the similarity of the polymers used in the claimed blends to those used by Wilhoit.

13. Claims 9-12 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney in view of Wilhoit as applied to claims 1,2, 4-8, 13-24, 26-30 and 36-41 above, and further in view of Sudo (EPO 0556034 A1).

Barney and Wilhoit are discussed above.

They fail to teach (bridged) cyclic olefin-containing resins.

Sudo teaches the use of (bridged) cyclic olefin-containing resins in medical instruments capable of maintaining medicament liquids in high quality (abstract). On pages 3 through 7, Sudo shows the (bridged) cyclic olefin monomers that applicants claim.

Barney, Wilhoit and Sudo are analogous because they all deal with polymeric materials that can be used to contain medical fluids.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the (bridged) cyclic olefin monomer-containing resins of Sudo in the containers suggested by the combination of Barney and Wilhoit in order to help assure that the high quality of the medical fluids contained therein would be maintained.

The motivation to employ the (bridged) cyclic olefin-containing resins of Sudo in the containers suggested by Barney and Wilhoit is found in the abstract of Sudo where the maintenance of medicament liquids of high quality is said to be associated with the use of the (bridged) cyclic olefin monomer-containing resins of Sudo. It is deemed desirable to maintain the quality of medical liquids by placing them in containers that assure such quality (per Sudo), while those containers are rupturable to mix their contents (per Barney) and puncture resistant (per Wilhoit).

***Response to Arguments***

14. The arguments advanced in Paper No. 8 have been rendered moot by the new rejections stated herein.

***Conclusion***

Any inquiry concerning this communication should be directed to Sandra M. Nolan, whose telephone number is 703/3089545. She can generally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

Her supervisor is Harold Pyon (703/308-4251). The fax number for the art unit is 703/305-5408. The receptionist answers 703/308-0661.



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